

REMARKS

Claims 1-3, 5 and 7-10 are pending in the subject application. Claims 5 and 8 have been amended. The amendments to claims 5 and 8 is supported by the specification as filed, and no new matter is presented. Favorable reconsideration in light of the remarks which follow is respectfully requested.

1. 35 U.S.C. §112 Rejections

Claims 8 and 10 have been rejected under 25 U.S.C. §112, second paragraph as being indefinite. The Office states that "In claim 8, it is unclear what is meant by 'composed of that in which'."

Applicants have amended claim 8 as suggested by the Office. Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. §102 Rejections

Claims 5 and 7 have been rejected under 35 U.S.C. §102(e) as being anticipated by Bell (US 6,179,872). The Office asserts that:

Bell is directed to a bipolar matt for use in tissue repair and reconstruction (Title).

As to claim 5, Bell teaches that objects can be made of bipolymers such as collagen (column 12, lines 15-20). Bell teaches that objects can be embedded in the nonwoven material to alter its tear properties such as fragments of resorbable polymers (column 10, lines 15-30). Bell teaches that resorbable polymers include poly-1-lactic acid (polylactic acid) and poly-1-glycolic acid (polyglycolic acid)(column 12, lines 27-33).

As to claim 7, Bell teaches that the matt of collagen material or composite matt may be washed by various mild methods such as 0.001-0.1 M hydrochloric acid (column 16, lines 15-23). Bell teaches that the washing step occurs after freeze drying and can be freeze dried again after the washing step (column 16, 25-30).

Applicants respectfully traverse.

Applicants claim, in claim 5, a collagen material in which a biocompatible substance that can be degraded and absorbed in the body is filled into a non-woven fabric-like matrix composed of that selected from the group consisting of polyglycolic acid, polylactic acid, copolymer of glycolic acid and lactic acid, polydioxanone,

copolymer of glycolic acid and trimethylene carbonate, and a mixture of polyglycolic acid and polylactic acid, wherein said collagen material has one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet state (for a thickness of 1 mm).

Applicants' collagen material provides advantages over the prior materials in that it possesses physical properties that allow suturing while still maintaining the biochemical properties inherently possessed by collagen, and in that it retains its shape for a certain period of time after application to the body. Applicants' collagen material can be used as alternative medical membranes and present no ethical problems, can be produced in a stable supply, prevent adhesion of the surgical wound following surgery, present no risk of infection, do not cause tissue degeneration, allow a controllable rate of degeneration following application, and promote regeneration of biomembranes.

In particular, Applicants collagen material has superior strength compared to prior collagen materials, including those of Bell. When a collagen material absorbs liquids such as saline or water, it begins to swell and becomes much weaker and easier to be broken. Thus, when used, for example, in surgical applications wherein sutures are placed through the material is sutured, holes made in prior materials are easily broken/torn. Thus, prior collagen materials are often difficult to suture.

Applicants have, thus, solved these problems by creating a collagen material having one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N even in the wet state. Applicants produce their materials by using polyglycolic acid, etc. and by using very high pressure of approximately 500 kgf/cm² in the production process. Applicants collagen material prevents swelling of the collagen component because the collagen component adheres very strongly to the polyglycolic acid, etc., which possesses hydrophobic properties. Thus, regardless of the level of surgeon's suturing skills, the present collagen material can be successfully used.

Bell, on the other hand, describes a bipolymer matt that can be made of bipolymers such as collagen. However, Bell does not describe or suggest Applicants' collagen material in which a biocompatible substance that can be degraded and absorbed in the body is filled into a non-woven fabric-like matrix wherein the collagen material has one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet state (for a thickness of 1 mm).

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

It is clear from the forgoing that each and every element of claim 5 is not set forth in Bell. Further these missing elements would not be inherent in the materials of Bell. As it has been established, and as set forth in MPEP §2112, The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). The missing elements would not necessarily be present in the materials of Bell.

Accordingly, it is respectfully submitted that claim 5 is not anticipated by Bell. Claim 7 depends from claim 5 and, likewise, is not anticipated by Bell. Reconsideration and withdrawal of the rejection is respectfully requested.

3. 35 U.S.C §103 Rejections

Claims 8 and 10 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bell (US 6,179,872) in view of Yasuhiko (WO 98/22157).

Applicants respectfully traverse. As set out above, Bell does not describe or suggest Applicants' collagen material in which a biocompatible substance that can be degraded and absorbed in the body is filled into a non-woven fabric-like matrix wherein the collagen material has one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet state (for a thickness of 1 mm).

The Office further acknowledges that Bell fails to teach that in the dry state, the collagen material has one-point support tensile force of at least 10 N and rupture resistance tensile force of at least 25 N and, in the wet state, a one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N as required by claim 10.

Yasuhiko, in combination with Bell, still does not teach Applicants' invention as set forth in claim 10.

Yasuhiko describes non-fibrous collagen layers in which collagen molecules are dispersed, in the form of monomers and oligomers, on the outside of the nonwoven collagen fabric multi-layered structure. Further, according to Yasuhiko, collagen molecules are also incorporated between the plate fibers of the nonwoven collagen fabric multi-layered structure. (Col. 4, lines 48-55 of US 6,277,397).

According to Applicants, the substance having biocompatibility is filled into the matrix by, for example, allowing it to seep in under reduced pressure (see page 19, lines 26-29; page 14, lines 1-10, step j). According to Yasuhiko, on the other hand, when the non-woven fabric-multi-layer structure is formed, a sheet-like mesh intermediate is left immersed in a collagen hydrochloric acid solution (col. 10, lines 32-39) and, thus, the collagen hydrochloric acid solution does not penetrate into the sheet-like mesh intermediate.

Thus, Bell in combination with Yasuhiko does not teach or suggest Applicants' collagen material in which a biocompatible substance that can be degraded and absorbed in the body is filled into a non-woven fabric-like matrix.

Thus, Applicants respectfully submit that claim 10 is patentable over Bell in view of Yasuhiko. Reconsideration and withdrawal of the rejection is respectfully requested.

Regarding claim 8, which ultimately depends from claim 5, Applicants respectfully submit that Bell fails to teach a collagen material Applicants' collagen material in which a biocompatible substance that can be degraded and absorbed in the body is filled into a non-woven fabric-like matrix, wherein the collagen material has one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet state as required by claim 7.

As set forth above, Yasuhiko, in combination with Bell does not teach or suggest Applicants' collagen material in which a biocompatible substance that can be degraded and absorbed in the body is filled into a non-woven fabric-like matrix.

Thus, Applicants respectfully submit that claim 8 is patentable over Bell in view of Yasuhiko. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

Reconsideration and allowance of claims 1-3, 5 and 7-10 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicants respectfully requests early consideration and allowance of the subject application.

Applicants conditionally petition for an extension of time to provide for the possibility that such a petition has been inadvertently overlooked and is required. As provided below charge Deposit Account No. **04-1105** for any required fee.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,



Lisa Swiszczy Hazzard (Reg. No. 44,368)
EDWARDS & ANGELL, LLP
P.O. Box 9169
Boston, MA 02209
Tel. No. (617) 517-5512